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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,139

02/27/2004

Kevin P. Connors

ALTU-1110

9270

72003

7590

05/11/2010

Cutera c/o MoFo

425 Market Street

San Francisco, CA 94105-2482

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

05/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,139	Applicant(s) CONNORS ET AL.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 10, 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 22, 23 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 22, 33 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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In response to the previous office action, applicant has filed a Declaration (hereinafter the Alexiades-Armenakas Declaration) Declaration by Dr. Macrene Alexiades-Armenakas (hereinafter Declarant). In paragraphs 1-3, Declarant discusses her education and current positions. In paragraph 4, Declarant states that she runs a laser surgery and research center that does studies on many light based skin tightening systems, including a system (the Titan system) purportedly covered by the instant patent application claims. In paragraph 5, Declarant states that “I own no stock in Cutera (the instant assignee) and I have no stake in the outcome of this proceeding” (parenthetical comments added) and further notes that her views are based on her expertise in the field. In paragraph 6, Declarant states that she has reviewed the application and the previous office action and believes that claim 15 is not obvious over the applied art. In paragraph 7, Declarant states the salient limitations of claim 15. In paragraph 8, Declarant states that she investigated the Titan system and states her belief that the treatment parameters recited in claim 15, particularly those related to the wavelength range are important for the ability of the product to tighten the skin, and that in her opinion these parameters are not rendered obvious by the applied art. In paragraph 9, Declarant states that she observed that the effects of the Titan system are “very consistent and very reproducible” and opines that this is due to “an optimal treatment wavelength range, which produces deeper heating and induces neoclastogenesis” and goes on to state that she has not previously observed such consistent results with other systems. In paragraph 10, Declarant sets forth the prior art references applied to instant claim 15. In paragraph 11, Declarant discusses her perception of the teachings of the Anderson et al reference and concludes that the reference would teach one of ordinary skill in the art to use a single wavelength, asserting that the teaching of the use of an “incoherent source is ambiguous since

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the output of an incoherent source can be filtered to generate narrowband light”. In paragraph 12, Declarant discusses her perception of the teachings of the Altshuler ’3042 reference and concludes that while this reference does teach wavelength ranges of 800-1800 nm; 900-1400 nm; and 1100-1250 nm, stating that these ranges would likely only result in superficial dermal injury and that the claimed range would not be used by one of ordinary skill in the art combining the Anderson et al and Altshuler ’3042 references. In paragraph 13, Declarant asserts that one of ordinary skill in the art would not derive the claimed treatment time from the reference combination, asserting that the treatment time is “[P]erhaps one of the least obvious aspects of the claimed method”. In paragraph 14, Declarant discussed her perception of the teachings of the Altshuler ’3780 reference, noting that the broadband range disclosed thereby would not render the claimed range obvious. In paragraph 15, Declarant discusses her perception of the teachings of the Fullmer and Vayenberg references, noting that neither of these references cure the perceived deficiencies of the base combination. In paragraphs 16 and 17, Declarant discusses the wavelength ranges disclosed by the Fullmer and Vayenberg references, stating that these ranges would not render the claimed range obvious. In paragraph 18, Declarant states that in her opinion, the combined references would not render the claimed wavelength range obvious.

The examiner will now analyze the Alexiades-Armenakas Declaration. The examiner has no comment regarding the statements in paragraphs 1-3. Regarding paragraph 4, the examiner notes the conspicuous absence of discussion of any device produced by Palomar, the assignee of the two Altshuler references. The examiner has no comment regarding the statements in paragraphs 5-8. Regarding paragraph 9, the examiner notes that this appears to be a statement of unexpected results, rather than non-obviousness per se. The examiner further notes that there is

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not enough evidence of record to establish any unexpected results of the claimed range.

Regarding paragraph 10, the examiner notes that the “ambiguity” surrounding the use of an incoherent source would lead one of ordinary skill in the art to believe that the use of a wavelength band, rather than a single wavelength would provide useful results. Regarding paragraph 11, the examiner notes that while Declarant may feel that the ranges recited by Altshuler '3042 would not produce the asserted unexpected results. However, this is problematic, as the range of 1100-1250 nm undeniably falls within the claimed range of “a wavelength band principally between 1050nm and 1850nm” and further the range of 900-1800 nm is also regarded as falling in this claimed range. It is further unclear how including the lower 150 nm of the latter range would somehow magically negate the efficacy of the upper 750 nm of the range, which would also be applied to the skin. Regarding paragraph 13, the examiner notes that Anderson et al teach the application of 10-150 joules of energy using 5-100 watts of power (see column 4, lines 40-48). This would require a treatment time of between 40 seconds (150 joules at 100 Watts) and 2 seconds (10 joules at 5 Watts). Thus applicant's opinion notwithstanding, treatment times as claimed are clearly taught by Anderson et al. Regarding paragraphs 14-17, the examiner notes that these references were not employed for the wavelength ranges they teach, thus any ranges taught by these references are not germane to the instant rejection.

Regarding applicant's arguments, these merely restate the points brought forth in the Alexiades-Armenakas Declaration, and are similarly unconvincing for the reasons set forth above.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17, 22, 33, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,120,497 to Anderson et al in combination with U.S. Patent Application Publication US 200410093042 to Altshuler et al. ('3042) and U.S. Patent Application Publication US 200210173780 to Altshuler et al. ('3780). Anderson et al. teach a method for treating wrinkles with radiation at depths from 100 microns to 1.2 millimeters (overlaps claim depth) using laser or incoherent radiation and specifically discloses the known property of collagen to shrink at temperatures from 60°C to 70°C (see column 5, lines 19-41), as well as the desirability of using wavelengths in the range of 1.3 to 1.8 microns, e.g. a band principally between 1,300 nm and 1,800 nm (see column 3, lines 28-37), and provides for cooling before and during the application of radiation to control the depth and temperature of treatment (see column 5, line 66 to column 6, line 14). Altshuler et al. '3042 teach a method and apparatus for treating tissue with light above 1050 nm which can be generated by an incandescent source (non-invasive wrinkle removal) in a region at depth by applying optical radiation thereto of a wavelength able to reach the depth of the region and of a selected relatively low power for a duration sufficient for the radiation to effect the desired treatment while

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concurrently cooling tissue above the selected region to protect such tissue (abstract). The irradiation source (Fig. 1, # 1) may be a radiant lamp, a halogen lamp, an incandescent lamp, an arc lamp, a fluorescent lamp, a light emitting diode, a laser (including diode and fiber lasers), the sun or other suitable optical energy source (paragraph 0044). Cooling is provided by a contact plate (Fig. 1, # 8) and may be made out of a suitable heat transfer material, and also, where the plate contacts tissue, of a material having a good optical match with the tissue. Sapphire is disclosed as an example of a suitable material for the plate. In some embodiments, the contact plate may have a high degree of thermal conductivity, for example, to allow cooling of the surface of the tissue by cooling mechanism (paragraph 0050). The irradiation time may vary from approximately 2 seconds to approximately 2 hours (paragraph 0012). The treatment times overlap those claimed and one skilled in the art would use a time appropriate to achieve the desired temperature based on the operating parameters of the radiation source. Cooling may be applied concurrently with the irradiation or prior to irradiation (paragraph 0011). The cooling of the epidermal layer in conjunction with irradiation inherently yields an inverted temperature gradient. Sensors or other monitoring devices may also be embedded in cooling mechanism, for example, to monitor the temperature, or determine the degree of cooling required by tissue, and be manually or electronically controlled (paragraph 0051). A skilled artisan knows that such control may be via a simple timer or feedback mechanism such as a temperature sensor and typically provides for a means of notification that the process has ended. Indicator lights and audible tones are known and obvious. Altshuler et al. '3042 further teach an irradiation wavelength of from 1050 to 1250 nanometers (paragraph 0010), which is well known to penetrate tissue from about 2-5 millimeters. A filter (Fig. 1, # 3) is included for wavelength

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selection. Altshuler et al. '3042 do not disclose cooling after termination of the treatment radiation. Altshuler et al. '3780 teach an apparatus and method for irradiating tissue with a cooled waveguide for cooling the tissue before, during and after irradiation. This clearly teaches a predetermined time after irradiation termination or the cooling would continue indefinitely. Neither Altshuler et al. '3042 nor Altshuler et al. '3780 disclose the specific temperature at which collagen shrinks. It would have been obvious to the artisan of ordinary skill to one skilled in the art to continue cooling the tissue following radiation as taught by Altshuler et al. '3780 while heating collagen in the method taught by Anderson et al., since importance of cooling to avoid damage to peripheral area and it is considered obvious to one of skill in the art, and such person would continue cooling to limit such damage, and to employ the incandescent source and filters of Altshuler et al. '3042 since Anderson recognizes that absorption occurs over a range of wavelengths. Thus, the combination of the known methodologies would clearly yield a predictable result. Both Altshuler et al. references provide a handpiece. To provide switches and indicators necessary for operation on the handpiece is well known and obvious, thus producing a method such as claimed.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Altshuler et al. ('3042) and Altshuler et al. ('3780). as applied to claim 15 above and further in view of U.S. Patent 5,885,274 to Fullmer et al. The Altshuler et al. and Anderson et al. teachings are discussed above, but do not teach the importance of the temperature of the filament. Fullmer et al. disclose a filament lamp for use in dermatological treatments including the use of a simmer voltage to maintain the temperature of the filament to allow faster rise time of the light pulses and to enhance the short pulses by the filament being in

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a warm condition (Col. 7, lines 42-45). It would have been obvious to one skilled in the art to use the simmer pulse (long pulse) as taught by Fullmer et al. in the method of Altshuler et al. '3042 in view of Altshuler et al. '3780 in Anderson et al. to improve the efficiency of the light source pulse integrity as suggested by Fullmer et al., thus producing a method such as claimed.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Altshuler et al. ('3042) and Altshuler et al. ('3780). as applied to claim 15 above and further in view of U.S. Patent Application Publication US 200510107850 to Vaynberg et al. The Altshuler et al. teachings are discussed above, but do not teach control of the light source using detected light from the source. Vaynberg et al. disclose a method and system for skin rejuvenation by heating collagen (paragraph 0037) using light from a non-coherent source. The light source is controlled using a light sensor (Fig. 1, # 135) that provides feedback to a controller (Fig. 1, # 130) to alter the pulse parameters (Paragraph 00 18). It would have been obvious to one skilled in the art to use the optical feedback as taught by Vaynberg et al. in the method of Altshuler et al. '3042 in view of Altshuler et al. '3780 in view of Anderson et al. to provide positive control of the treatment parameters, thus producing a method such as claimed.

Applicant's arguments filed February 10, 2010 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769